

Remarks

I. Amendment to the Claims

Support for claims 20-23, 26-28, 35-38, and 41-43 are found at page 2, line 6 to page 4, line 37 and Example 6. Support for claims 24, 25, 39, and 40 are found at page 6, line 35 to page 7, line 23. Support for claims 29-34 and 44-49 are found at page 1, line 9 to page 3, line 6.

II. Rejections under 35 U.S.C. § 112, 1st Paragraph—Written Description

Claims 13-17 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey that the inventors had possession of the claimed invention at the time the application was filed. Office Action at pages 2-4. In the Office Action, the Examiner alleged that the specification does not disclose a homolog or a fragment of SEQ ID NO: 13 while the specification provides an adequate written description for SEQ ID NO: 13 and a polynucleotide encoding SEQ ID NO: 13. *Id.* In particular, the Examiner noted that:

[t]he specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of polynucleotide encoding a representative number variants/fragments of SEQ ID NO: 13, as per Lilly by structurally describing 'structural features common to the members of the genus, which features constitute a substantial portion of the genus' have to [be] disclosed. In this application, such structural features common to the claimed variants/fragments have not been disclosed.

Office Action at page 6 (emphasis in original).

Applicants respectfully disagree with the Examiner's rejection. However, in order to expedite the prosecution and not in acquiescence of the rejection, all claims were

canceled, rendering the rejection moot. Applicants reserve the right to pursue the subject matter in related applications. The newly submitted claims are drawn to a method of preventing or treating a Group B streptococcal disease or disorder comprising administering a composition comprising an isolated peptide which comprises an amino acid sequence at least 95% similar to SEQ ID NO: 13, wherein peptide induces antibodies that specifically bind to a polypeptide consisting of SEQ ID NO: 13. Insofar as the rejection applies to the newly submitted claims, Applicants respectfully traverse.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention based on the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02. The Federal Circuit recently re-emphasized the well-settled principle of law that "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed,'" *Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000).

The Federal Circuit in *Eli Lilly* set forth several tests for whether a claimed genus is adequately described, one of which was the "representative number of *species*" test. *See Regents of the University of California v. Eli Lilly*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Moreover, the Federal Circuit and the PTO have acknowledged that a specification may adequately describe a genus even though it fails to describe a single species falling within the genus. *Eli Lilly* at 1406; M.P.E.P. 2163 (II)(A)(3)(a)(ii) at 2100-169. Furthermore, the written description requirement for a claimed genus can be satisfied, *e.g.*, by disclosure of relevant, identifying characteristics, *i.e.*, structure or other

physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that the Applicant was in possession of the claimed genus. *See Regents of the University of California v. Eli Lilly*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)

Applicants respectfully point out that the new claims recite the "structural features common to the members of the genus, which features constitute a substantial portion of the genus." "The structural feature common to the members of the genus" is the amino acid sequence at least 95% similar to SEQ ID NO: 13. The common structural feature is further coupled with a functional characteristic, *i.e.*, the peptide can induce antibodies that specifically bind to a polypeptide consisting of SEQ ID NO: 13. Examples of the peptide comprising an amino acid sequence at least 95% similar to SEQ ID NO: 13, found in *S. agalactiae* M732, and specifically binds to antibodies raised against a polypeptide consisting of SEQ ID NO: 13 can be found in different strains of *Streptococcus agalactiae* (Group B *Streptococcus*), as shown in Table 1.

TABLE 1

Accession number and name	Length of aa sequence of subject	E-value	Number of subjects in query that matched query	Identity between query and subject (%)
YP_330488 <i>S. agalactiae</i> A909	482	0	482/482	100
NP_688922 <i>S. agalactiae</i> 2603V/R NP_736354 <i>S. agalactiae</i> NEM316 ZP_00781622 <i>S. agalactiae</i> 18RS21	482	0	481/482	99
ZP_00788507 <i>S. agalactiae</i> CJB111	482	0	480/482	99
ZP_00782129 <i>S. agalactiae</i> H36B	482	0	481/482	99

The specification notes that while "[t]he present invention is described with reference to Group B Streptococcal strain M732[,] ... all GBS strains and many other bacterial strains are likely to include related peptides or proteins having amino acid sequence homology with the peptide of M732." Specification at page 3, lines 20-30.

In view of the amendments and examples shown above, Applicants respectfully argue that the new claims properly recite structural properties by functional characteristics coupled with a known or disclosed correlation between function and structure. According to the Federal Circuit and PTO, these are sufficient to show that Applicants had possession of the claimed invention based on the specification as filed. Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

III. Rejections under 35 U.S.C. § 112, 1st Paragraph--Enablement

Claims 13-17 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable a person skilled in the art to which it pertains to make and use the invention commensurate with the scope of the claims. Office Action at page 7. On pages 7 and 10 of the Office Action, the Examiner has acknowledged that the specification enables the claimed polypeptide comprising SEQ ID NO: 13 and "a method of treatment of Group B streptococcal infections...." The Examiner, however, alleged that the specification does not enable methods of treating or preventing bacterial infections with SEQ ID NO: 13 or variants or fragments of SEQ ID NO: 13. *Id.*

Applicants respectfully disagree. In order to expedite the prosecution and not in acquiescence of the Examiner's rejection, however, all claims were canceled, rendering the rejection moot. The newly added claims recite a method of treating or preventing a

Group B streptococcal disorder or disease. Applicants reserve the right to pursue the canceled subject matter in related applications. In view of these amendments, Applicants respectfully request that the rejection be withdrawn.

IV. Rejections under 35 U.S.C. § 112, 2nd Paragraph

Claims 13-17 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particular point out and distinctly claim the subject matter which Applicants regard as their invention. *Id.* at pages 10-11. In order to expedite the prosecution, claims 13-17 were canceled, rendering the rejection moot. Applicants respectfully request that the rejection be withdrawn.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Eric K. Steffe
Attorney for Applicants
Registration No. 36,688

Date: 4/25/07

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
641576_4.DOC